■ 10/088405 ⁴²
JC10 Rec'd PCT/PTO 1 8 MAR 2002

EXPRESS MAIL LABEL EV077493871US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: CHANDRASEKAR, Baskaran et al.

Serial No.: Not Yet Assigned

Filed: 18 March 2002

Title: LOCAL DELIVERY OF 17-BETA ESTRADIOL FOR PREVENTING VASCULAR

INTIMA HYPERPLASIA AND FOR IMPROVING VASCULAR ENDOTHELIUM

FUNCTION AFTER VASCULAR INJURY

Docket: 410718.90395

INFORMATION DISCLOSURE STATEMENT

[X]1. Pursuant to 37 CFR 1.97(b) [within 3 mos. of filing or prior to 1st Office Action]

[]2. Certification Pursuant to 37 CFR 1.97(c) [before Final Office Action or Allowance]

[]3. Fee Payment Pursuant to 37 CFR 1.97(c) before Final Office Action or Allowance]

[]4. Petition, Certification & Petition Fee Payment Pursuant to 37 CFR 1.97(d) [before issue fee payment]

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

The following are submitted in the above-identified application in compliance with 37 CFR 1.97 & 1.98:

[X]5.A list of documents on form PTO-1449, together with copies of each identified document and a translation or a concise explanation of each non-English language document is enclosed herewith. (These are the references cited in the PCT International Search Report.)

This paper is submitted in accordance with:

- []7. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
 - []8. The required certification made in item 11 below; or
 - []9. The \$230.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 14 below.

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[]10. 37 CFR §1.97(d): [before issue fee payment]; and

- (a) This is a petition for consideration of the subject Information Disclosure Statement. The petition fee (\$130.00) required by 37 CFR 1.17(i)(1) is authorized in item 14 below. (Direct this letter to: "Attn.: PETITIONS EXAMINER" and if applicable, include batch locator information: e.g. "Allowed Files, Batch, Date of Allowance______"), and
- (b) The required Certification is stated in item 11 below.

[]11.Certification

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- []12. Each item of information contained in this Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement; or
- []13. No item of information contained in this Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the person signing this document after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three (3) months prior to the filing of this Statement.
- [X]14. Please charge all applicable fees associated with the submittal of this Information Disclosure Statement to Deposit Account No. 17-0055. An original and two (2) copies of this document are enclosed.

Respectfully submitted,

Jean C. Baker Reg. No. 35,433

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Express Mail No. EV077493871US

Form PTO-1449 (Rev. 2-88)

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EXAMINER

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 410718.90395 SERIAL NO. **UNASSIGNED**

APPLICANT

CHANDRASEKAR, Baskaran et al.

FILING DATE

(Use several sheets if necessary)

INFORMATION DISCLOSURE STATEMENT

BY APPLICANT

18 March 2002 **U.S. PATENT DOCUMENTS** DATE CLASS SUBCLASS FILING DATE DOCUMENT NUMBER NAME * EXAMINER'S INITIA 177 1 5,376,652 12/27/94 Norman 514 2 Ungs 514 182 5,866,561 2/2/99 FOREIGN PATENT DOCUMENTS CLASS SUBCLASS TRANSLATION DATE COUNTRY DOCUMENT NUMBER NO YES 98/56312 12/17/98 wo 3 4 3/9/00 WO 00/12147

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) YOON YOUNG-SUP ET AL: "Local intraluminal infusion of oestradiol containing liposome in rat cartoid balloon injury model." EUROPEAN HEART JOURNAL, vol. 19, no. ABST. SUPPL., August 1998 (1998-08), page 616; XP001014473; XXth Congress of the European Society of Cardiology; Vienna, Austria; August 22-26, 1998; ISSN: 0195-668X 7 ZHANG Y-Q ET AL: "EFFECTS OF GENDER AND ESTRADIOL TREATMENT ON FOCAL BRAIN ISCHEMIA", BRAIN RESEARCH, AMSTERDAM, NL, vol. 784, no. 1/2, 16 Feb 1998 (1998-02-16), pages 321-324, XP000884355; ISSN: 0006-8993 8 KAUFFMAN RAYMOND F ET AL: "Comparative effects of local vs. systemic administration of estrogen upon vascular responses to balloon injury." CIRCULATION, vol. 92, no. 8 SUPPL., 1995, page 1628; XP001014766; 68th Scientific Session of the American Heart Association; Anaheim, CA; USA; November 13-16, 1995; ISSN: 0009-7322

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DATE CONSIDERED

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 410718.90395 SERIAL NO. **UNASSIGNED**

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICANT CHANDRASEKAR, Baskaran et al. 18 March 2002 (Use several sheets if necessary) **U.S. PATENT DOCUMENTS** SUBCLASS DATE CLASS FILING DATE DOCUMENT NUMBER NAME EXAMINER'S INITIAL FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER DATE COUNTRY CLASS . SUBCLASS TRANSLATION NO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; May 1999 9 (199-05); PERROT-APPLANAT M: "Qestradiol and proliferation of vascular cells." Database accession no. PREV200000507148; XP002177140; abstract & THERAPIE (LONDON), vol. 54, no. 3, May 1999 (1999-05), pages 333-337, ISSN: 0040-5957 DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1995 MIKKOLA 10 TOMI ET AL: "17-beta-estradiol stimulates prostacyclin, but not endothelin-1, production in human vascular endothelial cells." Database accession no. PREV199598355996; XP002177141; abstract & JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM, vol. 80, no. 6, 1995, pages 1832-1836; ISSN: 0021-972X 11 DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996 MIKKOLA TOMI ET AL: "Effect of physiological encentrations of estradiol on PGI-2 and NO in endothelial cells. Database accession no. PREV199799286811; XP002177142; abstract & MATURITAS, vol. 25, no. 2, 1996, pages 141-147; ISSN: 0378-5122 CHANDRASEKAR, BASKARAN (1) ET AL: "Coronary artery endothelial protection following local delivery of 12 17-beta estradiol during balloon angioplasty: A potential new pharmacological approach to improve long-term outcome of angioplasty." JOURNAL OF AMERICAN COLLEGE OF CARDIOLOGY, (FEB., 2000) VOL. 35, NO. 2, SUPPL. A, PP. 58A, MEETING INFO .: 29TH ANNUAL SCIENTIFIC SESSION OF THE AMERICA COLLEGE OF CARDIOLOGY, ANAHEIM, CA, USA MARCH 12-15, 2000; XP001015229 13 SELZMAN, CRAIG H. ET AL: "Estrogen replacement inhibits intimal hyperplasia and the accumulation and effects of transforming growth factor .beta.1", J. SURG. RES. (1998), 80(2), 380-385; XP001014759 14 KEANY J. F. ET AL: "17BETA-ESTRADIOL PRESERVES ENDOTHELIAL VASODILATOR FUNCTION AND LIMITS LOW-DENSITY LIPOPROTEIN OXIDATION IN HYPERCHOLESTEROLEMIC SWINE" CIRCULATION, AMERICAN HEART ASSOCIATE, DALLAS, TX, US., vol 89, no. 5, May 1994 (1994-05), pages 2251-2259; XP001014735; ISSN: 0009-7322 DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SE RVICE, PHILADELPHIA, PA, US; 1996; KUBLIK 15 HEIKE ET AL: "Nasal absorption of 17-beta-estradiol from different cyclodextrin inclusion formulations in sheep." Database accession no. Prev199799383935; xp002177143; abstract & EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, vol. 42, no. 6, 1996, pages 320-324; ISSN: 0939-6411

EXAMINER DATE CONSIDERED

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